

Commonwealth of Massachusetts
Center for Health Information & Analysis (CHIA)
Non-Governmental Application for Case Mix Data

This form is required by all Applicants, except Government Agencies as defined in [957 CMR 5.02](#). All Applicants must also complete the Data Management Plan, attached to this Application. The Application and the [Data Management Plan](#) must be signed by an authorized signatory of the organization. This Application and the Data Management Plan will be used by CHIA to determine if your organization may receive CHIA data. Please be sure the documents are completed fully and accurately. You may wish to consult the Evaluation Guide that CHIA will use to review your documents. Prior to receiving CHIA Data, the organization must execute the [Data Use Agreement](#). You may wish to review that document as you complete these forms.

NOTE: In order for your application to be processed, you must submit the required application fee. Please consult the fee schedule for the appropriate fee amount. A [remittance form](#) with instructions for submitting the application fee is available on the CHIA website.

All attachments must be uploaded to IRBNet with your Application. All applications documents can be found on the [CHIA website](#) in Word and/or PDF format.

I. GENERAL INFORMATION

APPLICANT INFORMATION	
Applicant Name:	Patricia M. Noga, PhD, RN
Title:	Vice President, Clinical Affairs
Organization:	Massachusetts Health & Hospital Association
Project Title:	The Impact of Sociodemographic Factors on Hospital Readmission Reduction Program Assessments for Massachusetts Hospitals
IRBNet ID:	
Mailing Address:	500 District Ave. Burlington, MA 01803-5085
Telephone Number:	(781) 262-6045
Email Address:	pnoga@mhalink.org
Names of Co-Investigators:	Mathew C. Reidhead, M.A./ Hospital Industry Data Institute (HIDI) of the Missouri Hospital Association
Email Addresses of Co-Investigators:	mreidhead@mhanet.com
Original Data Request Submission Date:	November 29, 2016
Dates Data Request Revised:	
Project Objectives (240 character limit):	Evaluate the extent to which standard risk-adjusted measures of 30-day readmissions used to determine penalties under the Hospital Readmission Reduction Program (HRRP) are influenced by the inclusion of patient-level and contextual measures of sociodemographic and community-level effects.
Project Research Questions (if applicable) Business Use Case(s):	1. To what extent does the inclusion of patient Medicaid status, ZIP code poverty, homeless status, and ZIP-level random effects influence risk-adjusted hospital assessments for readmission performance in 30-day measures for

	<p>acute myocardial infarction, congestive heart failure, pneumonia, chronic obstructive pulmonary disease, total hip and knee arthroplasty, and coronary artery bypass graft patients?</p> <p>2. Are hospital characteristics such as safety-net status, high DSH, high SSI, and high dual-eligible case mix associated with significant reductions in estimated risk-standardized readmission rates after controlling for social determinants?</p> <p>3. Does evidence from Massachusetts hospitals support the policy position that the HRRP disproportionately penalizes hospitals that care for larger percentages of indigent patients?</p>
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II. PUBLIC INTEREST & PROJECT SUMMARY

1. Briefly explain why completing your project is in the public interest.

<p>Risk adjustment for publicly-reported health outcome measures is intended to allow for meaningful comparisons of measured quality differences between hospitals that are attributable to characteristics of the hospitals, as opposed to differing characteristics of the patients they care for or random variation.¹ Risk adjustment for patient-level clinical acuity and basic demographic factors such as age and gender are commonplace.²⁻⁷ However, a growing body of research emerges around individual- and community-level social factors associated with hospital readmission risk.⁸⁻¹⁶ Taken as a whole, evidence and associated theory suggest that relationships between social determinants and readmission risk are not often mediated by the effects of traditional hospital-based care. With these conditions, an expert panel convened by the National Quality Forum made recommendations in August 2014 suggesting that appropriate social determinant measures be included in risk-adjustment algorithms used for public reporting and other accountability applications.¹⁷ This research is intended to provide insight on comparisons of between-hospital quality differences in 30-day readmissions performance for selected condition- and procedure-specific measures after adjusting for sociodemographic status (SDS); and inform an ongoing national policy debate around the current decision by the Centers for Medicare & Medicaid Services (CMS) to exclude SDS factors from the models used to determine penalties under the HRRP.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Krumholz, H., et al. <i>Standards for statistical models used for public reporting of health outcomes</i>. An American Heart Association scientific statement from the quality of care and outcomes research interdisciplinary writing group. Cosponsored by the council on epidemiology and prevention and the stroke council. Endorsed by the American College of Cardiology Foundation. <i>Circulation</i>. January 24 2006, 113(3), 456-462. 2. Krumholz, H., Normand, S., Keenan, P., Lin, Z., Drye, E., Bhat, K., et al. (2008, April). (Yale University/Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, CT). <i>Hospital 30-day heart failure readmission measure</i>. Baltimore (MD): Centers for Medicare & Medicaid Services. 3. Krumholz, H., Normand, S., Keenan, P., Desai, M., Lin, Z., Drye, E., et al. (2008, June). (Yale University/Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, CT). <i>Hospital 30-day acute myocardial infarction readmission measure</i>. Baltimore (MD): Centers for Medicare & Medicaid Services. 4. Krumholz, H., Normand, S., Keenan, P., Desai, M., Lin, Z., Drye, E., et al. (2008, June). (Yale University/Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, CT). <i>Hospital 30-day pneumonia readmission measure</i>. Baltimore (MD): Centers for Medicare & Medicaid Services. 5. Grosso, L., Lindenauer, P., Wang, C., Savage, S., Potteiger, J., Abedin, Z., et al. (2011, September). (Yale University/Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, CT). <i>Hospital-level 30-day readmissions following admission for an acute exacerbation of chronic obstructive pulmonary disease</i>. Baltimore (MD): Centers for Medicare & Medicaid Services. 6. Grosso, L., Curtis, J., Lin, Z., Geary, L., Vellanky, S., Oladele, C., Ott, L., et al. (2012, June). (Yale University/Yale-New Haven Hospital Center for
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Outcomes Research and Evaluation, New Haven, CT). *Hospital-level 30-day all-cause risk-standardized readmission rate following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)*. Baltimore (MD): Centers for Medicare & Medicaid Services.

7. Horwitz, L., Partovian, C., Lin, Z., Herrin, J., Grady, J., Conover, M., Montague, J., et al. (2012, July). (Yale University/Yale-New Haven Hospital Center for Outcomes Research and Evaluation, New Haven, CT). *Hospital-wide all-cause unplanned readmission measure*. Baltimore (MD): Centers for Medicare & Medicaid Services.
8. Nagasako, E., Reidhead, M., Waterman, B. & Dunagan, W. (2014). Adding socioeconomic data to hospital readmissions calculations may produce more useful results. *Health Affairs*, 33(5), 786-791.
9. Hu, J., Gonsahn, M. & Nerenz, D. (2014). Socioeconomic status and readmissions: Evidence from an urban teaching hospital. *Health Affairs*, 33(5).
10. Joynt, K., Orav, E. & Jha, A. (2011). Thirty-day readmission rates for Medicare beneficiaries by race and site of care. *JAMA*, 305(7), 675-681.
11. Bernheim, S., Spertus, J., Reid, K., Bradley, E., Desai, R., Peterson, E., et al. (2007). Socioeconomic disparities in outcomes after acute myocardial infarction. *Am Heart J*, 153(2), 313-319.
12. Calvillo-King, L., Arnold, D., Eubank, K., Lo, M., Yunyongying, P., Stieglitz, H., et al. (2013). Impact of social factors on risk of readmission or mortality in pneumonia and heart failure: Systematic review. *J Gen Intern Med*, 28(2), 269-282.
13. McGregor, M., Reid, R., Schulzer, M., Fitzgerald, J., Levy, A. & Cox, M. (2006). Socioeconomic status and hospital utilization among younger adult pneumonia admissions at a Canadian hospital. *BMC Health Serv Res*. 6, 152.
14. Berenson, J. & Shih, A. (2012, December). *Higher readmissions at safety-net hospitals and potential policy solutions*. New York: Commonwealth Fund.
15. Joynt, K. & Jha, A. (2011). Who has higher readmission rates for heart failure, and why? Implications for efforts to improve care using financial incentives. *Circ Cardiovasc Qual Outcomes*, 4(1), 53-59.
16. Joynt, K. & Jha, A. (2013). Characteristics of hospitals receiving penalties under the hospital readmissions reduction program. *JAMA*, 309(4), 342-343.
17. National Quality Forum. (2014, August 15). *Technical report: Risk adjustment for socioeconomic status or other sociodemographic factors*. Retrieved from http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_Sociodemographic_Factors.aspx

2. Has an Institutional Review Board (IRB) reviewed your project?

- Yes, a copy of the approval letter and protocol must be **attached** to this Application
- No, this project is not human subject research and does not require IRB review.

3. If your project has not been reviewed by an IRB, please **attach** a brief (1-2 page) description of your project including the methodology, objectives, and research questions.

III. DATA FILES REQUESTED [Applicants seeking 2015 data only should skip to Question 2]

1. FY 2004 – 2014 Data: Please indicate the Case Mix files from which you seek data, the Level(s), the year(s) of data requested, and your justification for requesting each file. Please refer to the [Case Mix Data Specifications](#) for details of the file contents.

CASE MIX FILES	Levels 1 – 6	Years Available 2004 - 2014
Inpatient Discharge	<input type="checkbox"/> Level 1 – 3 Digit Zip Code <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) + 5 Digit Zip Code <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input checked="" type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL: Hierarchical models will be nested at patients' 5-digit ZIP and fixed effects will include ZIP-level socioeconomic variables as indicators of non-clinical contextual risk factors. Unique patient identifiers are required to identify patients longitudinally in readmission studies as	Year(s) of Data Requested: FY 2011 – FY 2014 Three-year study period with one year prior data for clinical history used in risk-adjustment.

	are dates of admission and discharge for the calculation of duration in days between discharge and next admission. Procedure and diagnosis codes are used in clinical risk-adjustment.	
Outpatient Observation	<input type="checkbox"/> Level 1 – 3 Digit Zip Code <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number <u>PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:</u> 	Year(s) of Data Requested:
Emergency Department	<input type="checkbox"/> Level 1 – 3 Digit Zip Code <input type="checkbox"/> Level 2 – Unique Physician Number (UPN) <input type="checkbox"/> Level 3 – Unique Health Information Number (UHIN) <input type="checkbox"/> Level 4 – UHIN and UPN <input type="checkbox"/> Level 5 – Date(s) of Admission; Discharge; Significant Procedures <input type="checkbox"/> Level 6 – Date of Birth; Medical Record Number; Billing Number <u>PLEASE PROVIDE JUSTIFICATION BELOW FOR REQUESTING THE CHOSEN LEVEL:</u> 	Year(s) of Data Requested:

2. FY 2015 Data: Beginning with fiscal year 2015, Massachusetts Acute Care Hospital and Case Mix and Charge Data (collectively Case Mix Data) are released in **Limited Data Set (LDS) files**. Please refer to the [Case Mix Data Specifications](#) for details of the file contents.

Please indicate the Case Mix files from which you seek data, the year(s) of data requested, and your justification for requesting each file.

CASE MIX LIMITED DATA SET FILES	Year(s) Of Data Requested Current Yrs. Available <input type="checkbox"/> 2015
<input type="checkbox"/> Inpatient Discharge	Please describe how your research objectives require Inpatient Discharge data:
<input type="checkbox"/> Outpatient Observation	Please describe how your research objectives require Outpatient Observation data:

<input type="checkbox"/> Emergency Department	Please describe how your research objectives require Emergency Department data:

Sections IV-IX must be completed by all Applicants requesting 2015 data. Applications that only include requests for prior years of data can skip to Section X.

IV. GEOGRAPHIC DETAIL

Please choose one of the following geographic options for MA residents:

<input type="checkbox"/> 3 Digit Zip Code (Standard)	<input type="checkbox"/> 3 Digit Zip Code & City/Municipality ***	<input type="checkbox"/> 5 Digit Zip Code ***	<input type="checkbox"/> 5 Digit Zip Code & City/Municipality ***
***Please provide justification for the chosen level of geographic detail if requesting something other than 3-Digit Zip Code only. Refer to specifics in your methodology:			

V. DEMOGRAPHIC DETAIL

Please choose one of the following demographic options:

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Race & Ethnicity***
*** If requested please, provide justification for requesting Race and Ethnicity. Refer to specifics in your methodology:	

VI. DATE DETAIL

Please choose one option from the following options for dates:

<input type="checkbox"/> Year (YYYY)(Standard)	<input type="checkbox"/> Month (YYYYMM) ***	<input type="checkbox"/> Day (YYYYMMDD)***
***Please provide justification for the chosen level of date detail if requesting Month or Day. Refer to specifics in your methodology:		

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VII. PHYSICIAN IDENTIFICATION NUMBERS (UPN)

Please choose one of the following options for Provider Identifier(s):

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed ID ***	<input type="checkbox"/> Board of Registration in Medicine # (BORIM) ***
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<p>***If requested please, provide justification for requesting Hashed ID or BORIM #. Refer to specifics in your methodology:</p>
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VIII. HASHED UNIQUE HEALTH IDENTIFICATION NUMBER (UHIN)

Please choose one of the following:

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> UHIN Requested ***
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<p>*** If requested please, provide justification for requesting UHIN. Refer to specifics in your methodology:</p>

IX. HASHED MOTHER’S SOCIAL SECURITY NUMBER

Please choose one of the following:

<input type="checkbox"/> Not Requested (Standard)	<input type="checkbox"/> Hashed Mother’s SSN Requested ***
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<p>*** If requested please, provide justification for requesting Hashed Mother’s SSN. Refer to specifics in your methodology:</p>
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X. DATA LINKAGE AND FURTHER DATA ABSTRACTION

Note: Data linkage involves combining CHIA Data with other databases to create one extensive database for analysis. Data linkage is typically used to link multiple events or characteristics that refer to a single person in CHIA Data within one database.

1. Do you intend to link or merge CHIA Data to other datasets?

- Yes
- No linkage or merger with any other database will occur

2. If yes, please indicate below the types of database to which CHIA Data be linked. [Check all that apply]

- Individual Patient Level Data (e.g. disease registries, death data)
- Individual Provider Level Data (e.g., American Medical Association Physician Masterfile)
- Individual Facility Level Data level (e.g., American Hospital Association data)
- Aggregate Data (e.g., Census data)
- Other (please describe):

3. If yes, describe the data base(s) to which the CHIA Data will be linked, which CHIA data elements will be linked; and the purpose for the linkage(s):

CHIA data will be linked with Nielsen-Claritas Pop-Facts Premier ZIP code-level socioeconomic status data to provide non-clinical risk-adjustment based on patients' community contextual factors.

4. If yes, for each proposed linkage above, please describe your method or selected algorithm (e.g., deterministic or probabilistic) for linking each dataset. If you intend to develop a unique algorithm, please describe how it will link each dataset.

Deterministic linkage with SAS v9.3 proc sql join statement.

5. If yes, please identify the specific steps you will take to prevent the identification of individual patients in the linked dataset.

Linking CHIA with Census-based Nielsen ZIP code information will not be used to identify patients or increase the risk of identification post-linkage. Final analyses will not include patient or record-level information, and will be limited to aggregate hospital and ZIP code-level results.

XI. PUBLICATION / DISSEMINATION / RE-RELEASE

1. Describe your plans to publish or otherwise disclose CHIA Data, or any data derived or extracted from such CHIA Data, in any paper, report, website, statistical tabulation, seminar, conference, or other setting. All publication of CHIA Data must comply with CHIA's cell size suppression policy, as set forth in the Data Use Agreement. Please explain how you will ensure that any publications will not display a cell less than 11, and no percentages or other mathematical formulas will be used if they result in the display of a cell less than 11.

The initial product of the analysis will be a report provided to MHA staff, which in turn will share it with MHA's board and other MHA policy groups such as MHA's Standing Committee on Finance, Clinical Issues Advisory Council, the Standing Committee on Public Affairs, and the Continuing Care Council. Depending on the findings and the deliberations of these MHA policy groups, the report or, more likely, excerpts or summaries of the report findings will be used in MHA advocacy on readmission penalty programs employed by CMS and other public and private payers. MHA advocacy efforts may include use of the MHA website, conferences, seminars, and printed materials. As part of its advocacy, MHA may provide hospital specific reports comparing the facility to peer groups or clinical categories. We will be alert to the cell size suppression policy in the course of any such communications. In addition, the methodology employed to derive risk-adjusted readmission rates suppresses estimation for hospitals with fewer than 25 individual cases (denominator) for the conditions and procedures modeled.

2. Do you anticipate that the results of your analysis will be published and/or publically available to any interested party? Please describe how an interested party will obtain your analysis and, if applicable, the amount of the fee, that the third party must pay.

To the extent that parties who are not MHA members or who are not the intended audience for advocacy communications such as those described have an interest in the analysis/report, we would consider such requests on a case-by-case basis. We do not anticipate charging any fees for such an analysis/report, unless the request would impose significant additional work burdens or expense to do so.

3. Will you use CHIA Data for consulting purposes?

- Yes
- No

4. Will you be selling standard report products using CHIA Data?

- Yes
- No

5. Will you be selling a software product using CHIA Data?

- Yes
- No

6. Will you be reselling CHIA Data in any format?

- Yes
- No

If yes, in what format will you be reselling CHIA Data (e.g., as a standalone product, incorporated with a software product, with a subscription, etc.)?

7. If you have answered “yes” to questions 4, 5 or 6, please describe the types of products, services or studies.

8. If you have answered “yes” to questions 4, 5, or 6, what is the fee you will charge for such products, services or studies?

XII. APPLICANT QUALIFICATIONS

1. Describe your qualifications (and the qualifications of your co-investigators) to perform the research described.

Dr. Noga was responsible for coordinating MA hospital participation in the Commonwealth Fund/IHI STAAR Project (State Action on Avoidable Rehospitalizations), represented MHA on the MHDC Care Transitions Workgroup, and directed the MHA Hospital Engagement Network effort to reduce readmissions and patient harm under a grant from the CMS Partnership for Patients. She co-authored State of the State: Reducing Readmissions in Massachusetts (March 2016).

The Hospital Industry Data Institute’s work is described in Section XIII of this application. Mr. Reidhead was a co-author of the 2014 Health Affairs article “Adding Socioeconomic Data To Hospital Readmissions Calculations May Produce More Useful Results,” [Health Affairs, 33(5), 786-791].

2. **Attach** résumés or curricula vitae of the Applicant/principal investigator, and co-investigators. (These attachments will not be posted on the internet.)

XIII. USE OF AGENTS AND/OR CONTRACTORS

Please note: by signing this Application, the Organization assumes all responsibility for the use, security and maintenance of the CHIA Data by its agents, including but not limited to contractors.

Third-Party Vendors. Provide the following information for all agents and contractors who will work with the CHIA Data.

Company Name:	Hospital Industry Data Institute (HIDI) of the Missouri Hospital Association
Contact Person:	Mathew C. Reidhead, M.A.
Title:	Vice President of Research and Analytics
Address:	4712 Country Club Dr. Jefferson City, MO 65109
Telephone Number:	573-893-3700 ext. 1331
E-mail Address:	mreidhead@mhanet.com
Organization Website:	http://web.mhanet.com

1. Will the agent have access to the CHIA Data at a location other than your location, your off-site server and/or your database?

- Yes, a separate Data Management Plan must be completed by each agent who will store CHIA Data
- No

Note from Applicant: As has been the case with the acquisition and use of prior CHIA case-mix files, MHA will not retain copies of nor have remote access to the requested case-mix data files as issued by CHIA other than to mail the unopened file to the Hospital Industry Data Institute (HIDI) immediately following receipt from CHIA. As previously advised by CHIA staff, the Data Management Plan will describe the HIDI Plan and the Data Management Plan for Non-Governmental Data Use application document will contain responses from HIDI.

2. Describe the tasks and products assigned to this agent for this project; their qualifications for completing the tasks; and the Organization's oversight of the agent, including how the Organization will ensure the security of the CHIA Data to which the agent has access.

All tasks performed by HIDI will be conducted under a standard business associate agreement struck between the Massachusetts Health and Hospital Association (MHA) and HIDI.

HIDI staff will conduct the hierarchical generalized logistic regression modeling required by the proposed research design. HIDI staff will provide MHA with hospital-level risk-standardized performance metrics established under the standard CMS and competing SDS-enriched methodologies and provide categorical comparisons of impact by hospital characteristics. HIDI has extensive experience in applied policy research and publication on the impact of SDS factors on readmission measures used in the HRRP.¹⁻²

HIDI is a 501(c)(3) not-for-profit corporation. Established in 1985, HIDI has provided data solutions including nationwide data collection, reporting, and analytics to create value and help healthcare facilities and public health agencies understand their market and their performance for more than three decades. Today, HIDI provides innovative data solutions to hospitals, health systems, state hospital associations, surgical centers, and state data agencies across the country.

HIDI has provided collection of inpatient and outpatient claims and creation of data sets used for analytics for more than 30 years. This experience has provided HIDI with the knowledge and skills to appropriately develop refined data collection, editing and reporting services to further health care service research and public health evaluation. As a company owned by the Missouri Hospital Association, HIDI has a strong understanding of health care policy and relevant legislative and regulatory issues.

HIDI collects, analyzes and disseminates data for approximately 1,400 hospitals nationwide and processes more than 45 million discharges annually. HIDI's state partners and Missouri hospital users can attest to HIDI's performance history to deliver complete, timely and accurate data to its customers.

HIDI operates as a HIPAA compliant business associate for multiple customers and organizations. Stewardship of PHI and confidentiality are core requirements of day to day operations.

Key security features of the HIDI platform include:

- Data encryption is included and used on all data at rest; SSL data encryption occurs during uploads and downloads, and
- Data recovery services are available.

References:

1. Nagasako, E., Reidhead, M., Waterman, B. & Dunagan, W. (2014). Adding socioeconomic data to hospital readmissions calculations may produce more useful results. *Health Affairs*, 33(5), 786-791.
2. Reidhead, M. (2016, February). Including Sociodemographic Factors in Risk-Adjusted Readmission Measures. HIDI HealthStats. Missouri Hospital Association. Hospital Industry Data Institute. Available at http://www.mhanet.com/mhaimages/SociodemFactos_HealthStats_0216.pdf

XIV. FEE INFORMATION

Please consult the [fee schedules](#) for Case Mix Data and select from the following options:

- Single Use
- Limited Multiple Use
- Multiple Use

Are you requesting a fee waiver?

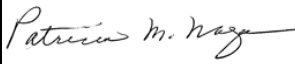
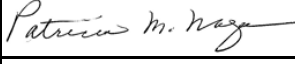
- Yes
- No

If yes, please refer to the [Application Fee Remittance Form](#) and submit a letter stating the basis for your request (if required). Please refer to the [fee schedule](#) for qualifications for receiving a fee waiver. If you are requesting a waiver based on the financial hardship provision, please provide documentation of your financial situation. Please note that non-profit status alone isn't sufficient to qualify for a fee waiver.

By submitting this Application, the Data Applicant attests that it is aware of its data use, privacy and security obligations imposed by state and federal law *and* is compliant with such use, privacy and security standards. The Data Applicant further agrees and understands that it is solely responsible for any breaches or unauthorized access, disclosure or use of any CHIA Data provided in connection with an approved Application, including, but not limited to, any breach or unauthorized access, disclosure or use by its agents.

Applicants requesting data from CHIA will be provided with data following the execution of a Data Use Agreement that requires the Data Applicant to adhere to processes and procedures aimed at preventing unauthorized access, disclosure or use of data.

By my signature below, I attest to: (1) the accuracy of the information provided herein; (2) that the requested data is the minimum necessary to accomplish the purposes described herein; (3) the Data Applicant will meet the data privacy and security requirements describe in this Application and supporting documents, and will ensure that any third party with access to the data meets the data use, privacy and security requirements; and (4) my authority to bind the organization seeking CHIA Data for the purposes described herein.

Signature: (Authorized Agent)	
Printed Name :	Patricia M. Noga, PhD, RN
Title:	Vice President, Clinical Affairs
Applicant's Signature:	
Name:	Patricia M. Noga, PhD, RN
Title:	Vice President, Clinical Affairs
Original Data Request Submission Date:	November 29, 2016
Dates Data Request Revised:	

Attachments. Please indicate below which documents have been attached to the Application and uploaded to IRBNet:

- 1. IRB approval letter or summary of project (if applicable)
- 2. Resumes of Applicant and co-investigators
- 3. Data Management Plan (for each institution that will store CHIA Data)